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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/016, 159	01/30/98	LEE	J 07004-002002

HM22/0926

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EXAMINER	
ART UNIT	PAPER NUMBER

1647

DATE MAILED: 09/26/00

This is a communication from the examiner in charge of your application.  
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### OFFICE ACTION SUMMARY

Responsive to communication(s) filed on 14 DEC 1999 - 30 AUG 2000

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire THREE (3) month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 1 - 10 is/are pending in the application.

Of the above, claim(s) 1, 2, 7 is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 3 - 6, 8 - 10 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claim(s) 1 - 10 are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of Reference Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413 (No. 16)

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

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-SEE OFFICE ACTION ON THE FOLLOWING PAGES--

1. The request filed on 14 December 1999 under 37 C.F.R. § 1.53(d) for a Continued Prosecution Application (CPA) based on parent application serial no. 09/016,159 is acceptable. A CPA has been established, and an action on the CPA follows.

5 The amendment filed on 19 August 1999 under 37 C.F.R. § 1.116 in the parent of the instant CPA was denied entry, *see* Paper No. 11, and applicant has not requested its entry in the instant continuing application. The application accordingly stands as amended by the amendments filed on 30 January 1998, 19 January 1999, 26 March 1999, and 30 August 2000.

10 Prosecution continues from the parent file. Because applicant has not engaged any of the outstanding rejections on the merits, they are maintained for the reasons of record as indicated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

15 2. With the examiner's concurrence, the elected claims from application serial no. 09/058,429, now abandoned, are imported into this application by the amendment filed 30 August 2000. The requirement for restriction between those claims (Group III as set forth in the Office letter mailed 9 December 1998, Paper No. 4) and the claims previously pursued in this application (Group II) is withdrawn.

20 All of claims 3-6 and 8-10 are now examined, and pursuant to the requirement imposed in Paper No. 4, claims 1, 2, and 7 remain withdrawn from consideration by the examiner, 37 C.F.R. § 1.142(b), as drawn to non-elected inventions.

25 3. The amendment filed 19 January 1999 is objected to under 35 U.S.C. § 132 because it introduces new matter into the specification. 35 U.S.C. § 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is the EPO receptor sequence data set forth in the sequence listing.

30 The rationale for admitting the recitation of explicit EPO-R sequences into the disclosure in this and its several parent applications was that it was understood in the art that there was a single human EPO-R amino acid sequence. Given such an understanding, the generic description of "the human EPO receptor" as set forth in the disclosure as filed would necessarily have conveyed to the artisan that the sequence set forth in the (first) sequence listing was the only one

that could have been contemplated. As is evident from a review of the remarks filed with the amendment of 19 August 1999, Paper No. 10, the rationale previously relied upon was in error because more than one EPO receptor amino acid sequence was known in the art at the time of the instant invention. The sequence listing consequently goes beyond the disclosure as filed because it selects one EPO receptor sequence for inclusion in the disclosure without any basis for the particular choice reflected in the sequence listing.

5 Applicant is required to cancel the new matter in the response to this Office action.

4. Claims 3, 5, and 8-10 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application 10 was filed, had possession of the invention as now claimed. This is a new matter rejection.

15 Claims 3, 5, 8, and 9 are subject to the rejection under this section as set forth at ¶ 3 of Paper No. 9. If the disclosure fails to demonstrate that the inventors were in possession of the genus of unglycosylated EPO receptor polypeptides, as previously stated by the examiner, it follows that it likewise fails to demonstrate that they were in possession of the genus of antibodies specific for such polypeptides.

Claim 10 is rejected under this section because it recites the particular EPO receptor amino acid sequence, SEQ ID NO: 5. The recitation of this sequence is not supported by the disclosure as filed for the reasons stated above in connection with the objection under 35 U.S.C. § 132.

20 5. Claims 3-5 and 8 are rejected under 35 U.S.C. § 102(b) as being anticipated by Harris *et al.* (JBC, 1992).

This rejection is maintained as to claims 3 and 5 for the reasons stated at ¶ 4 of Paper 25 No. 9.

Claims 4 and 8 are anticipated by Harris because the reference describes the production of antibodies specific for an unglycosylated hEPO-R polypeptide, an "EREx" fusion produced in *E. coli.*, and teaches that the antibodies block the binding of radioiodinated EPO to the cellular receptor (abstract). Because the antibodies were raised against an *E. coli* product and bind to the portion of the receptor responsible for its interaction with EPO, *i.e.*, the extracellular domain, it reasonably appears that the prior art antibodies necessarily and inherently meet all of the functional 30 limitations of claims 4 and 8.

6. Claims 3-6 and 8-10 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Harris (*JBC*, 1992) in view of D'Andrea '808.

Claims 3 and 5 remain unpatentable over the cited art for the reasons elaborated at ¶ 5 of Paper No. 9.

5 As to claims 4, 6, and 8-10, the relevant teachings of Harris are as discussed in the paragraphs above, and those of D'Andrea, at ¶¶ 6 and 7 of Paper No. 4. Harris does not describe the use of a polypeptide consisting of only the extracellular domain of hEPO-R as an immunogen, nor does it describe solid-phase assays employing the antibodies it discloses.

It would have been obvious to one of ordinary skill in the art at the time the invention was 10 made to produce a secreted receptor polypeptide according to the teachings of D'Andrea, using an *E. coli* expression system, as described by Harris; to make therewith a monoclonal or polyclonal antibody according to the method taught by D'Andrea; and to purify the antibodies according to conventional practice in the art because the artisan would reasonably have expected 15 any of such antibodies to be useful in the immunoblot methods described in the '808 patent. The artisan would have expected the bacterial expression product to be useful for the production of native EPO-R-specific antibodies because Harris demonstrates that the use of a similar polypeptide affords antibodies having such specificity. It further would have been obvious to employ any such antibody in any conventional immunoassay as was known in the art, *e.g.*, an ELISA, thus to practice the invention of claim 6, because the artisan would reasonably have expected any of such 20 antibodies to be useful for the quantitation of the EPO receptor polypeptide. The claimed invention would have been *prima facie* obvious as a whole at the time it was made, especially in the absence of evidence to the contrary.

7. The examiner believes that he has addressed all pertinent arguments. No claim is allowed.

8. Any inquiry concerning this communication should be directed to David Fitzgerald, who can be reached by any of the following means:

Telephone (703) 308-3934

Fax

All formal papers (703) 308-4242

Informal communications (703) 308-0294

e-mail (note PTO policies below) david.fitzgerald@uspto.gov

Inquiries of a general nature should be directed to the Technology Center 1600 receptionists at (703) 308-0196.



DAVID L. FITZGERALD

PRIMARY EXAMINER

ART UNIT 1647

20 September 2000

The best time to reach Examiner Fitzgerald is from 9 a.m. to 4 p.m. (Eastern). If he cannot take a call, a message may be left on his voicemail. Should attempts to reach him be unsuccessful, the supervisor for this Art Unit, Gary Kunz, may be reached at (703) 308-4623.

Most official papers and all informal communications may be submitted to the PTO by fax. For specific policies, refer to 37 C.F.R. § 1.6 and the notice published at 1096 O.G. 30. To facilitate their receipt and handling, please —

- ♦ Call the examiner when you send an urgent communication.
- ♦ Do not send a duplicate copy by mail or courier.

Any Internet e-mail communications will be made of record in the application file. PTO employees cannot engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. § 122. This policy is more fully set forth in the Interim Internet Usage Policy published in the PTO's *Official Gazette* on 25 February 1997 at 1195 O.G. 89.